

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Wannamacher et al.

Serial No.: 09/523,271

Filed: March 10, 2000

For: DEGLYCOSYLATED RICIN TOXIN A  
CHAIN VACCINE

Art Unit: Not yet assigned

Examiner: Not yet assigned

Atty. Docket: 0207-0004

11011 U.S. PTO  
09/960315  
09/24/01

#5  
12.18.01

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Listed on the accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that an exhaustive search has been made, or that there does not exist information more material to the examination of the present patent application. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will review art of record in all 35 U.S.C. § 120 priority documents.

- ☒ 1. This Information Disclosure Statement is being filed within three months of the U.S. filing date OR before the mailing date of a first Office Action on the merits. No certification or fee is required.
- ☐ 2. The Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection or Notice of Allowance.
- ☐ a. I hereby certify that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).
- ☐ b. I hereby certify that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56 (c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).
- ☐ c. Attached is our check no. \_\_\_\_\_ in the amount of \$200.00 in payment of the fee under 37 C.F.R. § 1.17(p).
3. This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of a Final Rejection or Notice of Allowance, but before payment of the Issue Fee. Applicants hereby petition that the Information Disclosure Statement be considered. Attached is our check no. \_\_\_\_\_ in the amount of \$130.00 in payment of the fee under 37 C.F.R. § 1.17(d)(1).
- a. I hereby certify that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).

- ☐b. I hereby certify that no item of information on this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).
- ☐4. Relevance of the non-English language document(s) is discussed in the present specification.
- ☐5. The document(s) was/were cited in a corresponding foreign application. An English language version of the foreign search report is attached for the Examiner's information.
- ☐6. A concise explanation of the relevance of the non-English language document(s) appears below:
- ☐7. The Examiner's attention is directed to co-pending U.S. Patent Application No. \_\_\_\_\_, filed \_\_\_\_\_, which is directed to related technical subject matter. The identification of this U.S. Patent Application is not to be construed as a waiver of secrecy as to that application now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited application and the art cited therein during examination.
- ☐8. Copies of the documents were cited by or submitted to the Office in Application No. \_\_\_\_\_, filed \_\_\_\_\_, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

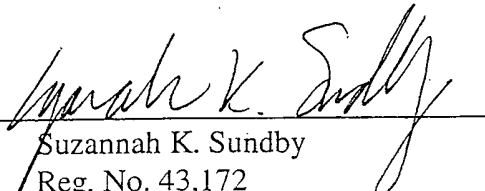
It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and to indicate in the official file wrapper of this patent application that the documents have been considered.

The Commissioner is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. **50-0622**. A duplicate copy of this paper is enclosed.

Respectfully submitted,

SHANKS & HERBERT

By: \_\_\_\_\_

  
Suzannah K. Sundby  
Reg. No. 43,172

Date: 2 August 2000

TransPotomac Plaza  
1033 N. Fairfax Street  
Suite 306  
Alexandria, VA 22314

FORM PTO 1449  <u>INFORMATION DISCLOSURE STATEMENT</u>	ATTY. DOCKET NO. 0207-0004	APPLICATION NO. 09/523,271	11011 U.S. PTO 09/960315 09/24/01
	APPLICANT(S) Wannemacher, et al.		
	FILING DATE March 12, 2000	GROUP Not Assigned	

## U.S. PATENT DOCUMENTS

EXAMINER'S INITIAL	Cite No.	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA1	5,453,271	9/26/95	Lemley, et al.			

## FOREIGN PATENT DOCUMENTS

EXAMINER'S INITIAL	Cite No.	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
							<input type="checkbox"/> Yes <input type="checkbox"/> No

## OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

EXAMINER'S INITIAL	Cite No.		Include Author, Title, Date, Pertinent, etc.
	AB	<u>1</u>	Blakely & Thrope, <u>Cancer Drug Delivery</u> 3:189-196 (1986).
	AC	<u>1</u>	Brugsch, <u>New England Journal of Medicine</u> 262:1039-1040 (1960).
	AD	<u>1</u>	Compton & Gall, <u>Medicine Legal Journal</u> 48:51-62 (1980).
	AE	<u>1</u>	Cookson & Nottingham, <u>Monthly Review Press</u> , New York, NY:259-282 (1969).
	AF	<u>1</u>	Fodstad, et al, <u>Breast Journal Cancer</u> 34:418-425 (1976).
	AG	<u>1</u>	Foxwell, et al., "The Preparation Of Deglycosylated Ricin By Recombination Of Glycosidase-Treated A- And B-Chains: Effects Of Deglycosylation On Toxicity And In Vivo Distribution" <u>Biochim. Biophys. Acta</u> 923:59-65 (1987).
	AH	<u>1</u>	Ghetie & Vitetta, "Recent Developments In Immunotoxin Therapy" <u>Cancer Drug Delivery</u> 2:191-198 (1994).
	AI	<u>1</u>	Ghetie & Vitetta, <u>Curr. Opin. Immunol.</u> 6:707-714 (1994).
EXAMINER			DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO 1449  <u>INFORMATION DISCLOSURE STATEMENT</u>	ATTY. DOCKET NO. 0207-0004	APPLICATION NO. 09/523,271
	APPLICANT(S) Wannemacher, et al.	
	FILING DATE March 12, 2000	GROUP Not Assigned

## OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS CONT.

EXAMINER'S INITIAL	Cite No.		Include Author, Title, Date, Pertinent, etc.
	AJ	<u>2</u>	Golde, et al., <u>Infect. Immun.</u> 65:882-889 (1997).
	AK	<u>2</u>	Hewetson, et al., "A Formalized Toxoid For Protection Of Mice From Inhaled Ricin" <u>Vaccine Res.</u> 4:179-187 (1995).
	AL	<u>2</u>	Lamb, et al, <u>Eur. J. Biochem.</u> 148:265-270 (1985).
	AM	<u>2</u>	Lemley & Wright, "Mice Are Actively Immunized After Passive Monoclonal Antibody Prophylaxis And Ricin Toxin Challenge" <u>Immunology</u> 76:511-513 (1992).
	AN	<u>2</u>	Lindstrom, et al., "An In Vitro Model For Toxin-Mediated Vascular Leak Syndrome: Ricin Toxin A Chain Increases The Permeability Of Human Endothelial Cell Monolayers" <u>Blood</u> 90:2323-2334 (1997).
	AO	<u>2</u>	Lord, et al., <u>FASEB J.</u> 8:201-208 (1984).
	AP	<u>2</u>	Lord, et al., "Ricin Cytotoxicity, Biosynthesis And Use In Immunoconjugates" <u>Prog. Medical Chemical</u> 24:1-28 (1987).
	AQ	<u>2</u>	O'Hare, et al. "Expression Of Ricin A Chain In <i>Eschericia Coli</i> " <u>FEBS Lett.</u> 216:8-73 (1987).
	AR	<u>2</u>	Roberts, et al., <u>J. Biol. Chem.</u> 15682-15686 (1985)
	AS	<u>2</u>	Soler-Rodriguez, "The Toxicity Of Chemically Deglycosylated Ricin A-Chin In Mice" <u>J. Immunopharmacol</u> 14:281-291 (1992).
	AT	<u>2</u>	Soler-Rodriguez, et al., "Ricin A-Chain And Ricin A-Chain Immunotoxins Rapidly Damage Human Endothelial Cells :Implications For Vascual Leak Syndrome" <u>Exp. Cell. Res.</u> 206:227-234 (1993).
EXAMINER			DATE CONSIDERED
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	APPLICANT(S) Wannemacher, et al.	
	FILING DATE March 12, 2000	GROUP Not Assigned

## OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS CONT.

EXAMINER'S INITIAL	Cite No.		Include Author, Title, Date, Pertinent, etc.
	AU	<u>3</u>	Thompson, et al., <u>Bact. Res.</u> 11:115-145 (1947).
	AV	<u>3</u>	Thorpe, et al., <u>Eur. J. Biochem.</u> 147:197-206 (1985).
	AW	<u>3</u>	Underwood, et al., <u>Immunology</u> 85:256-261 (1995).
	AY	<u>3</u>	Van Heiningen, F. Ed., <u>In Molecular Action of Toxins and Viruses</u> , Amsterdam: Elsevier Biomedical Press: 51-105 (1982).
	AX	<u>3</u>	Vitetta, et al, "Immunotoxins: Magic Bullets Or Misguided Missiles" <u>Trends Pharmacol. Science</u> 14:148-154 (1993).
	AZ	<u>3</u>	Wawrzynczak, et al., "Comparative Biochemical, Cytotoxic And Pharmacokinetic Properties Of Immunotoxins Made With Native Ricin A Chain, Ricin A <sub>1</sub> Chain And Recombination Ricin A Chain" <u>Int. J. Cancer</u> 47:130-135 (1991).
	BA	<u>3</u>	Wood, et al, "Preproabrin: Genomic Cloning, Characterization And The Pexpression Of The A-Chain In <i>Escherichia Coli</i> " <u>Eur. J. Biochem.</u> 198:723-732 (1991).
	BB	<u>3</u>	Zajtchuk, R. and R.F. Bellamy Eds., <u>Textbook of Military Medicine</u> , Office of the Surgeon General, Department of the Army, USA: 631-642 (1997).
EXAMINER		DATE CONSIDERED	
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Wannamacher

Serial No. 09/523,271

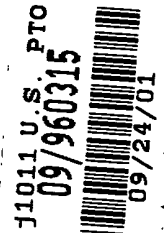
Filed: March 10, 2000

For: Deglycosylated Ricin Toxin A-Chain Vaccine

Art Unit: 1644

Examiner: J. Roark

Atty. Dkt. No.: 0207-0004  
(RIID 99-12)



**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Honorable Commissioner of  
Patents and Trademarks  
Washington, D.C. 20231

Sir:

Submitted herewith on Form PTO-1449 is a listing of documents known to the Applicants in compliance with the requirements of 37 C.F.R. § 1.56. Copies of the documents are also being submitted herewith. This Supplemental Information Disclosure Statement is a continuation of the Applicant's Information Disclosure Statement filed on August 3, 2000 in connection with the above-captioned application.

Applicants do not waive any rights to appropriate action to establish patentability over any of the listed documents should they be applied as references against the claims of the present application.

This statement should not be construed as a representation that more material information does not exist or that an exhaustive search of the relevant art has been made.



CERTIFICATION UNDER 37 C.F.R. § 1.97(e)(1)

I hereby certify that the items of information contained in this Supplemental Information Disclosure Statement were cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the accompanying Supplemental Information Disclosure Statement. These references were cited in a PCT Written Opinion mailed December 11, 2000, and applicants do not waive any rights to appropriate action to establish patentability over any of the listed documents should they be applied as references against the claims of the present application.

Please note that US Patent Number 5,453,271 was previously cited in an Information Disclosure Statement filed on August 3, 2000 in this application and, therefore, is not attached hereto.

Entry of these references in the record of the prosecution of the above-identified application is respectfully requested.

It is believed that no fees are due for consideration of this Supplemental Information Disclosure Statement. The Commissioner is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 210380, referencing Attorney Docket No. 0207-0004 (RIID 99-12).

Respectfully submitted,

SHANKS & HERBERT

By: 

Suzannah K. Sundby  
Reg. No. 43,172

Date: February 14, 2001

TransPotomac Plaza  
1033 N. Fairfax Street  
Suite 306  
Alexandria, VA 22314

FOR TO 9  INFORMATION DISCLOSURE STATEMENT	ATTY. DCKET NO. 0207-0004	APPLICATION NO. 09/523,271
	APPLICANT(S) Wannamacher, et al.	
	FILING DATE March 10, 2000	GROUP 1644

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
	AA1	5,453,271	09-26-95	Lemley Paul v, et al.			

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
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							<input type="checkbox"/> Yes <input type="checkbox"/> No
							<input type="checkbox"/> Yes <input type="checkbox"/> No
							<input type="checkbox"/> Yes <input type="checkbox"/> No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AB1		Griffiths G. D. et al., Local and systemic responses against ricin toxin promoted by toxoid or peptide vaccines alone or in liposomal formulations' Vaccine, GB, Butterworth Scientific. Guildford, Vol. 16, no. 5, 1 March 1998 (1998-03-01), pages 530-535, XP004106967 ISSN: 0264-410X.
	AC1		Griffiths G. D. et al. Comparison of the quality of protection elicited by toxoid and peptide liposomal vaccine formulations against ricin as assessed by markers of inflammation' Vaccine GB, Butterworth scientific. Guildford, vol. 17, no. 20-21, 4 June 1999 pages 2562-2568, XP004169666 ISSN: 0264-410X.
	AD1		Lemley Paul V et al., Identification and characterization of a monoclonal antibody that neutralizes ricin toxicity in vitro and in vivo. Hybridoma, vol. 13 no. 5, 1994, pages 417-421, XP000960308 ISSN: 0272-457X.

EXAMINER

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Wannamacher

Serial No. 09/523,271

Filed: March 10, 2000

For: Deglycosylated Ricin Toxin A-Chain Vaccine

Art Unit: 1644

Examiner: J. Roark

Atty. Dkt. No.: 0207-0004  
(RIID 99-12)



INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Listed on the accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

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- ☒ c. Please charge Account No. 210380, Reference No. 0207-0004 (RIID 99-12) in the amount of \$180.00 in payment of the fee under 37 C.F.R. § 1.17(p).
- ☐ 3. This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of a Final Rejection or Notice of Allowance, but before payment of the Issue Fee. Applicants hereby petition that the Information Disclosure Statement be considered. Attached is our check no. \_\_\_\_\_ in the amount of \$130.00 in payment of the fee under 37 C.F.R. § 1.17(i)(1).
- ☐ a. I hereby certify that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).
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- ☐4. Relevance of non-English language document(s) is disclosed in the present specification.
- ☐5. The document(s) was/were cited in a corresponding foreign application. An English language version of the foreign search report is attached for the Examiner's information.
- ☐6. A concise explanation of the relevance of the non-English language document(s) appears below:
- ☐7. The Examiner's attention is directed to co-pending U.S. Patent Application No. \_\_\_\_\_, filed \_\_\_\_\_, which is directed to related technical subject matter. The identification of this U.S. Patent Application is not to be construed as a waiver of secrecy as to that application now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited application and the art cited therein during examination.
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The Commissioner is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 210380, Reference No. 0207-0004 (RIID 99-12).

Respectfully submitted,

SHANKS & HERBERT

By: Suzannah K. Sundby  
Suzannah K. Sundby  
Reg. No. 43,172.

Date: 16 March 2001

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1033 N. Fairfax Street  
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Alexandria, VA 22314  
703-386-6134

FORM P-449  <u>INFORMATION DISCLOSURE STATEMENT</u>	ATTY. DOCKET NO. 0207-0004	APPLICATION NO. 09/523,271
	APPLICANT(S) Wannamacher, et al.	
	FILING DATE March 10, 2000	GROUP 1644

11011 U.S. PTO  
09/960315  
09/24/01

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
	AA1	5,626,844	5-6-97	Lemley Paul, et al.			

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
							<input type="checkbox"/> Yes <input type="checkbox"/> No
							<input type="checkbox"/> Yes <input type="checkbox"/> No
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							<input type="checkbox"/> Yes <input type="checkbox"/> No
							<input type="checkbox"/> Yes <input type="checkbox"/> No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)


EXAMINER

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